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(54) Gel seal for a surgical trocar apparatus

Gel-Dichtung für einen chirurgischen Trokar-Apparat

Gel d'étancheité pour un appareil trocar chirurgical

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EP 1 629 787 B1

Description

BACKGROUND

1. Field of the Disclosure

[0001] The present disclosure relates to surgical devices and more particularly to a seal assembly for use with a surgical access device during a minimally invasive surgical procedure. For examples of such surgical access devices see WO 03/011154 and WO 2004/043275.

2. Description of the Related Art

[0002] Minimally invasive surgical procedures including both endoscopic and laparoscopic procedures permit surgery to be performed an organs, tissues and vessels far removed from an opening within the tissue. Laparoscopic and endoscopic procedures generally require that any instrumentation inserted into the body be sealed, i.e. provisions must be made to ensure that gases do not enter or exit the body through the incision as, for example, in surgical procedures in which the surgical region is insufflated. These procedures typically employ surgical instruments which are introduced into the body through a cannula. The cannula has a seal assembly associated therewith. The seal assembly provides a substantially fluid tight seal about the instrument to preserve the integrity of the established pneumoperitoneum.

[0003] Minimally invasive procedures have several advantages over traditional open surgery, including less patient trauma, reduced recovery time, reduced potential for infection, etc... However, despite its recent success and overall acceptance as a preferred surgical technique, minimally invasive surgery, such as laparoscopy, has several disadvantages. In particular, the maintenance of the seal about the surgical instrument has proved to be difficult in certain procedures, e.g., in procedures requiring extensive manipulation of the long narrow endoscopic instruments within a remote site. In addition, known seal devices are deficient in closing the opening defined by the seal in the absence of an instrument.

[0004] The state of the art includes also catheter introducers that include seals. See, for example, US-A-3402710 and US-A-5514109 in which it is advocated to use an elastomer or an encapsulated gel as the material of construction of a sealing element.

SUMMARY

[0005] Accordingly, the present invention is defined in claim 1 below, and the present disclosure is directed to a seal assembly for use with an access device during a surgical procedure. The seal assembly includes a housing having a passageway therethrough dimensioned to permit passage of a surgical instrument and being adapted for mounting to a trocar device, and a seal comprising a gel material and being mounted to the housing across the passageway. The seal includes inner seal portions defining an access channel dimensioned to form a substantial sealing relation with an object therethrough and substantially close in the absence of the surgical instrument. The seal comprises a second material having a hardness greater than a hardness of the gel material. The gel material may be a urethane gel, a silicon gel, gels incorporating super absorbent polymers, alginates, gum Arabic, polymer hydrogels or a copolymer thereof, or any combination of these materials. A lubricious coating may be applied to the gel material.

[0006] The surgical access device includes an access member defining a central longitudinal axis and having a central opening dimensioned for passage of an object, and a seal member mounted to the access member and being adapted to permit passage of the object. The seal member includes first and second seal materials. The first material may comprise a relatively soft gel while the second seal material is more rigid than the soft gel of the first material to stabilize the seal member and provide a substantial sealed relation with the object. The second seal material may comprise an elastomer material and/or a fabric material.

[0007] The seal member includes a first seal and a second seal. The first seal comprises a relatively soft gel material while the second seal comprises a material being more rigid than the soft gel material so stabilize the seal member and provide a substantial sealed relation with the object. The soft gel material of the first seal may comprise one of a urethane gel or a silicone gel. The material of the second seal element can be selected from elastomers and fabrics.

[0008] The first seal includes distinct inner portions defining an access channel for permitting passage of an object in substantial sealed relation therewith. In one embodiment, the second seal element includes inner portions adapted to permit passage of the surgical instrument. The inner portions of the second seal element define an opening adapted to form a sealed relation with a surgical instrument inserted therethrough. The first seal is mounted to the second seal or the second seal element is at least partially embedded within the first seal. The second seal element may define a general dome-shaped configuration.

The second seal element may include one of a duck-bill seal, conical seal and septum seal. The first seal element may be adapted for lateral movement relative to the longitudinal axis of the access member.

BRIEF DESCRIPTION OF THE DRAWING(S)

[0009] Preferred embodiments of the present invention will be better appreciated by reference to the drawings wherein:

FIGS. 1 - 2 are perspective views of a cannula assembly and a seal assembly;

FIG. 3 is a perspective view with parts separated of

the cannula and seal assemblies of FIG. 1;
FIG. 4 is a side cross-sectional view of the cannula and seal assemblies; FIG. 5 is a perspective view illustrating the seal assembly incorporated within the cannula housing; and
FIGS. 6-13 are side cross-sectional views of alternate embodiments of the seal assembly of FIG. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

[0010] The illustrated seal assembly, either alone or in combination with a seal system internal to a cannula assembly, provides a substantial seal between a body cavity of a patient and the outside atmosphere before, during and alter insertion of an object through the cannula assembly. Moreover, the seal assembly of the present invention is capable of accommodating objects of varying diameters, namely instruments from about 4.5 mm to about 15 mm, by providing a gas tight seal with each instrument when inserted. The flexibility of the present seal assembly greatly facilitates endoscopic surgery where a variety of instruments having differing diameters are often needed during a single surgical procedure. The seal assembly may be further adapted to substantially close in the absence of a surgical instrument to maintain the integrity of the insufflated peritoneal cavity.

[0011] The seal assembly contemplates the introduction and manipulation of various types of instrumentation adapted for insertion through a trocar and/or cannula assembly while maintaining a fluid tight interface about the instrumentation to preserve the atmospheric integrity of a surgical procedure from gas and/or fluid leakage. Specifically, the seal assembly accommodates angular manipulation of the surgical instrument relative to the seal axis. This feature of the present disclosure desirably minimizes the entry and exit of gases and/or fluids to/from the body cavity. Examples of instrumentation include clip appliers, graspers, dissectors, retractors, staplers, laser probes, photographic devices, endoscopes and laparoscopes, tubes, and the like. Such instruments will be collectively referred to herein as "instruments or instrumentation".

[0012] Moreover, the seal assembly may be readily incorporated into an access device, such as a conventional trocar device or cannula housing to provide the device with zero-closure and/or sealing around an instrument or other object.

[0013] The seal assembly may also be adapted to receive and form a seal about a physician's arm or hand during a hand-assisted laparoscopic procedure. In this application, the seal assembly is a component of an access member which is introduced within the body to provide access to underlying tissue in, e.g., the abdominal cavity.

[0014] Referring now to the drawings, in which like reference numerals identify identical or substantially similar parts throughout the several views, FIGS. 1-2 illustrate the seal assembly 100 of the present disclosure mounted to an access device such as cannula or trocar assembly 200. Cannula assembly 200 may be any conventional cannula suitable for the intended purpose of accessing a body cavity and typically defines a passageway permitting introduction of instruments therethrough. Cannula assembly 200 is particularly adapted for use in laparoscopic surgery where the peritoneal cavity is insufflated with a suitable gas, e.g., CO_2, to raise the cavity wall from the internal organs therein. Cannula assembly 200 is typically used with an obturator assembly (not shown) which may be blunt, a non-bladed, or a sharp pointed instrument positionable within the passageway of the cannula assembly 200. The obturator assembly is utilized to penetrate the abdominal wall or introduce the cannula assembly 200 through the abdominal wall, and then subsequently is removed from the cannula assembly to permit introduction of the surgical instrumentation utilized to perform the procedure through the passageway.

[0015] Cannula assembly 200 includes cannula sleeve 202 and cannula housing 204 mounted to an end of the sleeve 202. Cannula sleeve 202 defines a longitudinal axis "a" extending along the length of sleeve 202. Sleeve 202 further defines an internal longitudinal passage dimensioned to permit passage of surgical instrumentation. Sleeve 202 may be formed of stainless steel or other rigid materials such as a polymeric material or the like. Sleeve 202 may be clear or opaque. The diameter of sleeve 202 may vary, but typically ranges from about 4.5 to about 15 mm for use with the seal assembly 100 of the present disclosure.

[0016] Cannula housing 204 includes two components, specifically, housing flange 206 which is attached to the proximal end of cannula sleeve 202 and main housing 208 as shown in FIGS. 3-4. Main housing 208 is connectable to housing flange 206 through a bayonet coupling consisting of radially spaced tongues 210 on the exterior of housing flange 206 and corresponding recesses 212 within the interior of main housing 208. Tongues 210 are receivable within recesses 212. Thereafter, housing flange 206 and main housing 208 are rotated to securely lock the tongues 210 within the recesses 212, Other conventional means, e.g., a threaded snap fit, ultrasonic welding or any other means envisioned by one skilled in the art including, e.g., adhesive means, may be incorporated to connect housing flange 206 and main housing 208. Main housing 208 further includes diametrically opposed housing grips 214 dimensioned and arranged for gripping engagement by the fingers of the user. Additionally or alternatively, suture anchors may extend from main housing 208. Although shown and described as two components, cannula housing 204 may be a single component and attached to cannula sleeve 202 by any of the aforementioned means. The housing flange 206, or the housing flange 206 and main housing 208, may be integrally formed with cannula sleeve 202.

[0017] With reference to FIG. 3, in conjunction with FIGS. 1-2, cannula housing 204 further includes valve

216. Valve 216 may be frusto-conical in shape and define an aperture for sealed reception of the instrument. In the alternative, valve 216 may be a flat disc-shaped valve, balloon valve, flapper valve, duck-bill valve etc... The valve 216 may comprise a flat disc-shaped, conical, or hourglass-shaped member including a fabric material molded with an elastomer. In a further alternative, valve 216 is preferably a fabric seal and is desirably arranged so as to have a constriction. For example, the valve may have the general shape of an hourglass. The fabric can be a woven material, a braided material, or a knitted material. The type of material is selected to provide a desired expansiveness. For example, a braid of varying end count and angle may be selected. A preferred material is a synthetic material such as nylon, Kevlar (Trademark of E.I. DuPont de Nemours and Company) or any other material that will expand and compress about an instrument inserted therethrough. The selected material desirably minimizes or prevents the formation of gaps when the instrument is introduced into the seal or valve 216. The material of valve 216 may be porous or impermeable to the insufflation gas. If porous, valve 216 may include a coating of a material which is impermeable to the insufflation gas or at least a portion of the valve may be coated. In addition, the fabric may be coated on its interior with urethane, silicon or other flexible lubricious materials to facilitate passage of an instrument or other object, such as the hand and arm, through the valve 216. In certain embodiments, the fabric is twisted about the axis "a" so as to form a constriction or closed portion. The fabric is desirably constructed of a material and/or arranged so that the fabric forms a constriction or closure. The seal may also be molded so as to have a constriction or may be knitted, braided or woven so as to have a constriction. Other arrangements for valve 216 are also envisioned. In further embodiments, valve 216 is omitted.

[0018] Referring now to FIGS. 3 - 4, in conjunction with FIGS. 1-2, seal assembly 100 will be discussed in detail. Seal assembly 100 includes seal housing, generally identified as reference numeral 102, and gel seal 104 which is disposed within the seal housing 102. Seal housing 102 houses the sealing components of the assembly and defines the outer valve or seal body of the seal assembly 100. Seal housing 102 defines central seal housing axis "b" which is preferably parallel to the axis "a" of cannula sleeve 202 and, more specifically, coincident with the axis "a" of the cannula. Seal housing 102 incorporates three housing components, namely, proximal, distal and inner housing components 106, 108, 110, respectively, which, when assembled together, form the seal housing 102. Assembly of housing components 106, 108, 110 may be effected by any of the aforementioned connection means discussed with respect to cannula housing 204. Although shown and described as three components, it is appreciated that seal housing 102 may be a single component having the gel seal mounted therein.

[0019] With particular reference to FIGS. 3-4, gel seal 104 will be discussed in detail. In the preferred embodiment, gel seal 104 is mounted to proximal housing component 106 through, e.g., conventional means, such as by adhering the gel seal 104 to the component 106 or molding the gel seal 104 in the component 106. Gel seal 104 is fabricated from an elastomer such as a soft urethane gel, silicone gel, etc. and preferably has compressible characteristics to permit the seal to receive objects having a variety of sizes, to conform and form a seal about the outer surface of the inserted object, and to close upon removal of the object. Gel seal 104 preferably includes a single slit 112 advantageously dimensioned to permit reception and passage of a surgical instrument. In particular, slit 112 opens to permit passage of the surgical instrument whereby the internal gel portions defining the slit 112 engage the instrument in sealed relation therewith. The slit 112 is further adapted to assume a substantially closed position upon removal of the instrument. In this position, the seal 104 prevents the egress of gaseous matter through seal housing 102. Slit 112 may have shapes other than that of a linear slit, such as "t"-shaped, "x" shaped, helical, etc.

[0020] Seal assembly 100 may be associated with, or joined to, cannula assembly 200 in a variety of ways. In a preferred embodiment, seal housing 102 of seal assembly 100 and cannula housing 204 of cannula assembly 200 are adapted to detachably engage each other, e.g., through a bayonet lock, threaded attachment, latching attachment, or like mechanical means. In further embodiments, cannula housing 204 and valve 216 may be omitted and seal assembly 100 may be removably or permanently attached to flange 206. The seal assembly may be mounted to cannula assembly 100 before during or after application of the cannula assembly within the operative site. Alternatively, the seal assembly 100 may be built within cannula housing 204 as depicted in FIG. 5. As a further alternative, seal assembly 100 may be incorporated within a housing of a hand access device utilized in hand -assisted laparoscopic procedures.

[0021] The use of the seal assembly 100 and cannula assembly 200 in connection with introduction of a surgical instrument will be discussed. Seal assembly 100 is mounted to cannula assembly 200 and cannula assembly 200 is introduced into an insufflated abdominal cavity. An object, e.g., an instrument, is inserted into seal assembly 100 through slit 112 whereby the portions defining the slit 112 stretch to accommodate the instrument diameter, as necessary. The instrument is distally passed through the valve 216 in sealed relation therewith and into the body cavity to perform the desired procedure. The instrument is removed and the slit 112 of the gel seal 104 substantially closes to a zero-closure position to maintain the integrity of the established pneumoperitoneum. Other instruments may be introduced through the seal assembly 100 and cannula assembly to perform further operative techniques as desired.

[0022] FIGS. 6-13 illustrate various alternate embodiments of the gel seal 104 of FIGS. 1-4. Each embodiment includes a seal assembly fabricated from a first generally

soft gel material and a second generally harder seal material which is mounted to or embedded within the soft gel material. The combination of materials of varying hardness aids in sealing instruments during manipulation. In one embodiment, the soft gel material may be any suitable material identified hereinabove in connection with the embodiment of FIGS. 1-4, including, for example a urethane gel, a silicon gel, gels incorporating super absorbent polymer, alginates, gum Arabic, polymer hydrogels or a copolymer thereof, or other flexible lubricous material, or any combination of these materials. In one preferred embodiment, the soft gel material comprises urethane. The second material mounted to, or embedded in, the soft gel material may include a relatively hard gel material, e.g., a urethane treated to be more rigid than the soft urethane or any of the aforementioned seal materials specifically treated to increase its respective rigidity. The second material may comprise any elastomeric material. Additionally or alternatively, the second material is a fabric material including a woven, braided or knitted material of the type discussed hereinabove in connection with the embodiment of FIGS. 1-4. The seal may be a flat septum seal having a first layer of resilient material and a second fabric layer juxtaposed relative to the first layer. The fabric layer may include a SPANDEX material.

[0023] With reference now to FIG. 6, one alternate embodiment of the seal assembly 300 includes base plate 302, soft urethane seal 304 mounted to the base plate 302 and fabric seal 306. Soft urethane seal 304 is mounted to base, plate 302 through conventional means including adhesives, cements, etc. Alternatively son seal 304 may be cast molded with base plate 302 during manufacture and secured to the base plate 302 during curing of the soft seal 304. Base plate 302 may be formed from an elastomer, preferably, urethane, having a greater rigidity than the urethane material of soft seal 304. Other elastomer materials are also envisioned. Base plate 302 defines an opening 308 dimensioned to permit passage of an object.

[0024] Fabric seal 306 is preferably embedded within the proximal end of soft urethane seal 304 of the gel seal assembly 300. For example, fabric seal 306 may be positioned within soft urethane seal 304 during manufacture of the seal whereby the fabric seal 306 is embedded upon a curing phase of the seal. Alternatively, fabric seal 306 may be secured to a proximal end of gel seal 304 with adhesives, cements etc. Fabric seal 306 defines an aperture 310 which permits reception of the object in sealed relation therewith.

[0025] Fabric seal 306 provides a degree of rigidity to gel seal 304 and may desirably assist in maintaining the gel seal 304 in its disc-shaped configuration. Moreover, the combination of fabric seal 306 and gel seal 304 defines a seal having enhanced adaptability to a variety of different diameter objects, e.g., instruments, and which maintains a seal upon offset manipulation of the object. Fabric seal 306 also serves as a secondary seal supplemental to the sealing functions of gel seal 304.

[0026] In a preferred embodiment, gel seal 304 includes a cored hole 312 disposed in the proximal end of gel seal 304. Cored hole 312 may extend completely through gel seal 304 or partially through the seal 302. In the partial arrangement of cored hole 312, cored hole 312 terminates in slit 314 which extends to the lower end of the seal 302. Cored hole 312 is advantageously dimensioned to facilitate reception and passage of an object, e.g., a surgical instrument through seal 300. Cored hole 312 and slit 314 may open to permit passage of the object whereby the internal gel portions defining the cored hole 312 and slit 314 engage the instrument in sealed relation therewith.

[0027] It is further envisioned that base plate 302, which incorporates a more rigid, e.g., elastomer material relative to the soft gel 304, may also serve as a seal in the event a larger sized object is positioned within seal assembly 300. In particular, the inner portions of base plate 302 defining opening 308 may readily adapt to form a seal about the inserted object.

[0028] Referring now to FIG. 7, another alternate embodiment of the gel seal assembly is disclosed. Gel seal assembly 400 is similar to the embodiment of FIG. 6 and further includes a duck-bill seal 402 embedded within the main body section of gel seal 404. Duck bill seal 402 may be cast within gel seal 404 during manufacture and curing of the gel seal 404. Duck bill seal 402 preferably includes an elastomeric material and has a pair of planar seal portions 406 which taper inwardly relative to the axis of the seal. In one embodiment, duck bill seal 402 is a zero-closure valve, i.e., it substantially closes in the absence of an instrument. In the alternative, planar seal portions 406 do not close completely as depicted in FIG. 7. With this embodiment, a small gel section 408 of soft urethane material is disposed adjacent the distal or outlet opening of duck bill seal 402 to provide zero closure capabilities. This small gel section 408 preferably incorporates a slit 410 to permit passage of the object. Alternately, a gel section 408 may be secured within the interior of duck bill seal 402 adjacent its distal end. A cored hole 412 preferably extends from the aperture of the fabric seal to gel section 408 and is in communication with slit 410 of the gel section 408. The duckbill seal 402 may be substituted with a conical seal.

[0029] FIG 8 illustrates a further embodiment of the embodiment of FIG. 7 where the duck bill seal 402 adjacent the proximal end of the seal 400 is in direct contact with the flat fabric seal 306 as shown. In addition, the size of the opening between the panel portions may be larger as shown in FIG. 8. It is also envisioned that the duck bill seal 402 may be substituted with a conical or frusto-conical seal of the type which defines an opening in its initial state and which expands upon passage of the object.

[0030] FIG. 9 illustrates an alternate embodiment of the seal assembly of the present disclosure. Gel seal assembly 500 includes flat fabric seal 502 embedded

within soft urethane seal 504 in a manner similar to the embodiment of FIG. 5. Soft seal 504 further includes central open area 506 which is devoid of gel material. Central open area 506 facilitates passage of larger diameter objects, e.g., a surgeon's hand or instrumentation through seal assembly 500. Mounted within central open area 506 and extending within base plate 508 is a duck bill seal 510. Duck bill seal 510 functions as a zero-closure valve, as discussed hereinabove.

[0031] FIG. 10 illustrates an alternate embodiment including a gel seal assembly 600 having soft gel seal 602, flat seal 604 embedded within the gel seal 602 and cylindrical insert 606 which is embedded within the soft gel seal 602. Gel seal 602 defines an internal slit 608 adjacent its proximal end for passage of the object. Flat seal 604 may be an elastomeric seal or a fabric seal. Cylindrical insert 606 may be made from an elastomer or from a gel material having a greater hardness than the material of soft gel seal 602. Flat seal 604 and insert 606 serve as a stabilizer for the seal assembly 600 by increasing the overall rigidity of the seal 600. Flat seal 604 also functions as a secondary seal supplementing the sealing functions of gel seal 602.

[0032] FIG. 11 illustrates yet another embodiment of seal assembly. Seal assembly 700 includes housing 702 and first and second flat seals 704,706 mounted adjacent a soft gel seal 710, Soft gel seal 710 is disposed within channel 708 and is adapted for radial movement within the channel 708. More specifically, gel seal 710 may move within channel 708 in the direction of directional arrows "Z" upon offset manipulation of the object, i.e., the soft gel seal 710 may free float within housing 702. A lubricious coating may be applied to gel seal 710 to facilitate this radial or traversing movement within channel 708. First and second seals 704,706 may be elastomeric or incorporate a fabric material. Seals 704,706 may include an aperture or incorporate a slit(s) to permit passage of the object. Alternatively, soft gel seal 710 may be mounted to either or both first and second flat seals 704,706 and may or may not be adapted for radial movement within housing 702. One or both of seals 704, 706 may be omitted. In the embodiments of FIGS. 6-13, the gel seal may be mounted for movement (axial or radial) within housing 702.

[0033] FIG. 12 illustrates another alternate embodiment of seal assembly. Gel seal assembly 800 includes soft seal 802 with a bowled recess 804 within the proximal end of the soft gel seal 802. The bowled recess 804 extends to a narrow slit 806 which terminates within the distal side of soft seal 802. Slit 806 permits the instrument to pass through the seal 802 in sealing relation therewith. Slit 806 closes in the absence of an instrument. Bowled recess 804 effectively removes gel material adjacent slit 806 to facilitate passage of the object.

[0034] FIG. 13 illustrates yet another further embodiment of seal assembly. Gel seal assembly 900 includes soft gel seal 902 and domed fabric seal 904 which is embedded within the gel seal 902. The central area 906 within domed fabric seal 904 may be filled with soft gel material or alternately free of material to facilitate passage of the object therethrough. In the embodiment of FIGS. 6-13, the gel seal may be mounted for movement within a housing.

Claims

1. A surgical access device for receiving a surgical instrument with a shaft diameter in a range of from 4.5 to 15 mm, which comprises:

   an access device (200) defining a longitudinal axis and having a passageway therethrough dimensioned to permit passage of the surgical instrument; and
   a seal assembly (300, 400, 500, 600, 700) including a first seal (304, 404, 504, 602, 710, 802, 902) comprising a gel material and being mounted to the access device across the passageway, the first seal including inner seal portions defining an access channel dimensioned to form a sealing relation with the surgical instrument when advanced along the passageway and the seal assembly including a second seal (306, 502, 604, 704, 706, 904) comprising a material mounted to, or at least partially embedded within, the gel material of the first seal and having a hardness greater than a hardness of the gel material, the second seal arranged to stabilise the first seal and to receive the surgical instrument in sealed relation with the second seal.

2. The surgical access device according to claim 1 wherein the gel material comprises a flexible lubricious material.

3. The surgical access device according to claim 1 or 2 wherein the gel material is a urethane gel, a silicon gel, gels incorporating super absorbent polymers, alginates, gum Arabic, polymer hydrogels or a copolymer thereof, or any combination of these materials.

4. The surgical access device according to claim 1 wherein the seal assembly comprises a lubricious coating.

5. The surgical access device according to any one of the preceding claims wherein the second seal is at least partially embedded in the first seal.

6. The surgical access device according to any one of claims 1 to 4 wherein the first seal element is mounted to the second seal element

7. The surgical access device according to claim 5

wherein the second seal is disposed at an upper surface of the first seal.

8. The surgical access device according to claim 7 wherein the first seal defines an opening extending downwardly away from the second seal.

9. The surgical access device according to claim 5 wherein the second seal is disposed at a lower surface of the first seal.

10. The surgical access device according to claim 9 wherein the second seal defines a concave surface.

11. The surgical access device according to claim 5 wherein the second seal comprises an insert embedded in the first seal.

12. The surgical access device according to claim 1 wherein the upper surface of the first seal defines an opening having a stepped shape.

13. The surgical access device according to claim 1 wherein an upper surface of the first seal defines a recess having a concave shape.

14. The surgical access device according to any one of the preceding claims wherein the second seal material comprises an elastomer material.

15. The surgical access device according to any one of claims 1 to 13 wherein the second seal material comprises a fabric material.

16. The surgical access device according to any one of claims 1 to 13 wherein the material of the second seal is selected from elastomers and fabrics.

17. The surgical access device according to claim 1 wherein the second seal comprises a fabric material and defines a general dome-shaped configuration.

18. The surgical access device according to claim 1 wherein the first seal element is adapted for lateral movement relative to the longitudinal axis of the access device.

19. The surgical access device according to any one of the preceding claims wherein the second seal element includes one of a duck-bill seal, conical seal and septum seal.

20. The surgical access device according to claim 1, wherein the second seal is embedded within the first seal.

21. The surgical access device according to claim 1, wherein the first seal is so as to close the passageway in the absence of the surgical instrument.

22. The surgical access device according to claim 21, wherein the first seal includes a slit (112) operable to permit passage of the surgical instrument and form a sealed relationship therewith and adapted to close upon removal of the surgical instrument.

23. The surgical access device according to any one of the preceding claims, wherein the second seal includes inner potions adapted to permit passage of the surgical instrument, the inner portions defining an opening (310) adapted to form a sealed relation with the surgical instrument inserted therethrough.

Patentansprüche

1. Chirurgische Zugangsvorrichtung zum Aufnehmen eines chirurgischen Instruments mit einem Schaftdurchmesser in einem Bereich von 4,5 bis 15 mm, welche umfasst:

eine Zugangsvorrichtung (200), die eine Längsachse definiert und einen Durchgangsweg **dadurch** aufweist, der bemessen ist, um einen Durchgang des chirurgischen Instruments zu erlauben; und
eine Abdichtanordnung (300, 400, 500, 600, 700) mit einer ersten Abdichtung (304, 404, 504, 602, 710, 802, 902), die ein Gelmaterial aufweist und über den Durchgangsweg an der Zugangsvorrichtung montiert ist, wobei die erste Abdichtung innere Abdichtabschnitte enthält, die einen Zugangskanal definieren, der bemessen ist, um eine Abdichtbeziehung mit dem chirurgischen Instrument zu bilden, wenn es entlang des Durchgangswegs vorgeschoben wird, und wobei die Abdichtanordnung eine zweite Abdichtung (306, 502, 604, 704, 706, 904) enthält, die ein Material aufweist, das an dem Gelmaterial der ersten Abdichtung montiert ist oder zumindest teilweise darin eingebettet ist, und eine Härte aufweist, die größer als eine Härte des Gelmaterials ist, wobei die zweite Abdichtung angeordnet ist, um die erste Abdichtung zu stabilisieren und das chirurgische Instrument in abgedichteter Beziehung mit der zweiten Abdichtung aufzunehmen.

2. Chirurgische Zugangsvorrichtung nach Anspruch 1, wobei das Gelmaterial ein flexibles schmierendes Material umfasst.

3. Chirurgische Zugangsvorrichtung nach Anspruch 1 oder 2, wobei das Gelmaterial ein Urethangel, ein Siliziumgel, Gele mit superabsorbierenden Polymeren, Alginaten, Gummi Arabicum, Polymerhydroge-

len oder ein Copolymer davon oder irgendeine Kombination dieser Materialien ist.

4. Chirurgische Zugangsvorrichtung nach Anspruch 1, wobei die Abdichtanordnung eine schmierende Beschichtung umfasst.

5. Chirurgische Zugangsvorrichtung nach einem der vorhergehenden Ansprüche, wobei die zweite Abdichtung zumindest teilweise in die erste Abdichtung eingebettet ist.

6. Chirurgische Zugangsvorrichtung nach einem der Ansprüche 1 bis 4, wobei das erste Abdichtelement an dem zweiten Abdichtelement montiert ist.

7. Chirurgische Zugangsvorrichtung nach Anspruch 5, wobei die zweite Abdichtung an einer oberen Oberfläche der ersten Abdichtung angeordnet ist.

8. Chirurgische Zugangsvorrichtung nach Anspruch 7, wobei die erste Abdichtung eine Öffnung definiert, die sich nach unten weg von der zweiten Abdichtung erstreckt.

9. Chirurgische Zugangsvorrichtung nach Anspruch 5, wobei die zweite Abdichtung an einer unteren Oberfläche der ersten Abdichtung angeordnet ist.

10. Chirurgische Zugangsvorrichtung nach Anspruch 9, wobei die zweite Abdichtung eine konkave Oberfläche definiert.

11. Chirurgische Zugangsvorrichtung nach Anspruch 5, wobei die zweite Abdichtung einen Einsatz aufweist, der in die erste Abdichtung eingebettet ist.

12. Chirurgische Zugangsvorrichtung nach Anspruch 1, wobei die obere Oberfläche der ersten Abdichtung eine Öffnung mit einer abgestuften Form definiert.

13. Chirurgische Zugangsvorrichtung nach Anspruch 1, wobei eine obere Oberfläche der ersten Abdichtung eine Aussparung mit einer konkaven Form definiert.

14. Chirurgische Zugangsvorrichtung nach einem der vorhergehenden Ansprüche, wobei das zweite Abdichtmaterial ein Elastomermaterial umfasst.

15. Chirurgische Zugangsvorrichtung nach einem der Ansprüche 1 bis 13, wobei das zweite Abdichtmaterial ein Fasermaterial umfasst.

16. Chirurgische Zugangsvorrichtung nach einem der Ansprüche 1 bis 13, wobei das Material der zweiten Abdichtung aus Elastomeren und Fasern ausgewählt ist.

17. Chirurgische Zugangsvorrichtung nach Anspruch 1, wobei die zweite Abdichtung ein Fasermaterial aufweist und einen allgemein kuppelförmigen Aufbau definiert.

18. Chirurgische Zugangsvorrichtung nach Anspruch 1, wobei das erste Abdichtelement für eine seitliche Bewegung relativ zu der Längsachse der Zugangsvorrichtung angepasst ist.

19. Chirurgische Zugangsvorrichtung nach einem der vorhergehenden Ansprüche, wobei das zweite Abdichtelement eine Schnabeldichtung, eine konische Dichtung oder eine Septumdichtung enthält.

20. Chirurgische Zugangsvorrichtung nach Anspruch 1, wobei die zweite Abdichtung in der ersten Abdichtung eingebettet ist.

21. Chirurgische Zugangsvorrichtung nach Anspruch 1, wobei die erste Abdichtung zum Schließen des Durchgangswegs in der Abwesenheit des chirurgischen Instruments vorgesehen ist.

22. Chirurgische Zugangsvorrichtung nach Anspruch 21, wobei die erste Abdichtung einen Schlitz (112) enthält, der betrieben werden kann, um einen Durchgang des chirurgischen Instruments zu erlauben und eine abgedichtete Beziehung damit zu bilden, und angepasst ist, um sich beim Entfernen des chirurgischen Instruments zu schließen.

23. Chirurgische Zugangsvorrichtung nach einem der vorhergehenden Ansprüche, wobei die zweite Abdichtung innere Abschnitte enthält, die angepasst sind, um einen Durchgang des chirurgischen Instruments zu erlauben, wobei die inneren Abschnitte eine Öffnung (310) definieren, die angepasst ist, um eine abgedichtete Beziehung mit dem chirurgischen Instrument, das **dadurch** eingeführt wird, zu bilden.

Revendications

1. Dispositif d'accès chirurgical pour recevoir un instrument chirurgical d'un diamètre d'arbre dans la plage de 4,5 à 15 mm, qui comprend:

   un dispositif d'accès (200) définissant un axe longitudinal et comportant un passage à travers celui-ci dimensionné pour permettre le passage de l'instrument chirurgical; et
   un ensemble d'étanchéité (300, 400, 500, 600, 700) comportant un premier joint (304, 404, 504, 602, 710, 802, 902) comprenant un matériau de gel et monté sur le dispositif d'accès à travers le passage, le premier joint comportant des portions de joint intérieures définissant un canal

d'accès dimensionné pour former une relation d'étanchéité avec l'instrument chirurgical lorsqu'elles sont avancées le long du passage, et l'ensemble d'étanchéité comportant un deuxième joint (306, 502, 604, 704, 706, 904) comprenant un matériau monté sur, ou au moins partiellement noyé dans le matériau de gel du premier joint et d'une dureté plus grande que la dureté du matériau de gel, le deuxième joint étant agencé pour stabiliser le premier joint et pour recevoir l'instrument chirurgical en une relation étanche avec le deuxième joint.

2. Dispositif d'accès chirurgical selon la revendication 1, dans lequel le matériau de gel comprend un matériau lubrifiant flexible.

3. Dispositif d'accès chirurgical selon la revendication 1 ou 2, dans lequel le matériau de gel est un gel d'uréthane, un gel de silicium, des gels incorporant des polymères super absorbants, alginates, gomme Arabique, hydrogels de polymère ou un copolymère de ceux-ci, ou toute combinaison de ces matériaux.

4. Dispositif d'accès chirurgical selon la revendication 1, dans lequel l'ensemble d'étanchéité comprend un revêtement lubrifiant.

5. Dispositif d'accès chirurgical selon l'une quelconque des revendications précédentes, dans lequel le deuxième joint est au moins partiellement noyé dans le premier joint.

6. Dispositif d'accès chirurgical selon l'une quelconque des revendications 1 à 4, dans lequel le premier élément d'étanchéité est monté sur le deuxième élément d'étanchéité.

7. Dispositif d'accès chirurgical selon la revendication 5, dans lequel le deuxième joint est disposé à une surface supérieure du premier joint.

8. Dispositif d'accès chirurgical selon la revendication 7, dans lequel le premier joint définit une ouverture s'étendant vers le bas au loin du deuxième joint.

9. Dispositif d'accès chirurgical selon la revendication 5, dans lequel le deuxième joint est disposé à une surface inférieure du premier joint.

10. Dispositif d'accès chirurgical selon la revendication 9, dans lequel le deuxième joint définit une surface concave.

11. Dispositif d'accès chirurgical selon la revendication 5, dans lequel le deuxième joint comprend un insert noyé dans le premier joint.

12. Dispositif d'accès chirurgical selon la revendication 1, dans lequel la surface supérieure du premier joint définit une ouverture d'une forme étagée.

13. Dispositif d'accès chirurgical selon la revendication 1, dans lequel une surface supérieure du premier joint définit un évidement d'une forme concave.

14. Dispositif d'accès chirurgical selon l'une quelconque des revendications précédentes, dans lequel le deuxième matériau de joint comprend un matériau élastomère.

15. Dispositif d'accès chirurgical selon l'une quelconque des revendications 1 à 13, dans lequel le deuxième matériau de joint comprend un matériau d'étoffe.

16. Dispositif d'accès chirurgical selon l'une quelconque des revendications 1 à 13, dans lequel le matériau du deuxième joint est sélectionné parmi des élastomères et des étoffes.

17. Dispositif d'accès chirurgical selon la revendication 1, dans lequel le deuxième joint comprend un matériau d'étoffe et définit une configuration générale en forme de dôme.

18. Dispositif d'accès chirurgical selon la revendication 1, dans lequel le premier élément de joint est conçu pour un mouvement latéral relativement à l'axe longitudinal du dispositif d'accès.

19. Dispositif d'accès chirurgical selon l'une quelconque des revendications précédentes, dans lequel le deuxième élément de joint comprend un parmi un joint en bec de canard, un joint conique et un joint de septum.

20. Dispositif d'accès chirurgical selon la revendication 1, dans lequel le deuxième joint est noyé dans le premier joint.

21. Dispositif d'accès chirurgical selon la revendication 1, dans lequel le premier joint est destiné à fermer le passage en l'absence de l'instrument chirurgical.

22. Dispositif d'accès chirurgical selon la revendication 21, dans lequel le premier joint comporte une fente (112) actionnable pour permettre le passage de l'instrument chirurgical et pour former une relation étanche avec celui-ci et est conçu pour fermer lors du retrait de l'instrument chirurgical.

23. Dispositif d'accès chirurgical selon l'une quelconque des revendications précédentes, dans lequel le deuxième joint comporte des portions internes conçues pour permettre le passage de l'instrument chirurgical, les portions internes définissant une ouver-

ture (310) conçue pour former une relation étanche avec l'instrument chirurgical inséré à travers celle-ci.

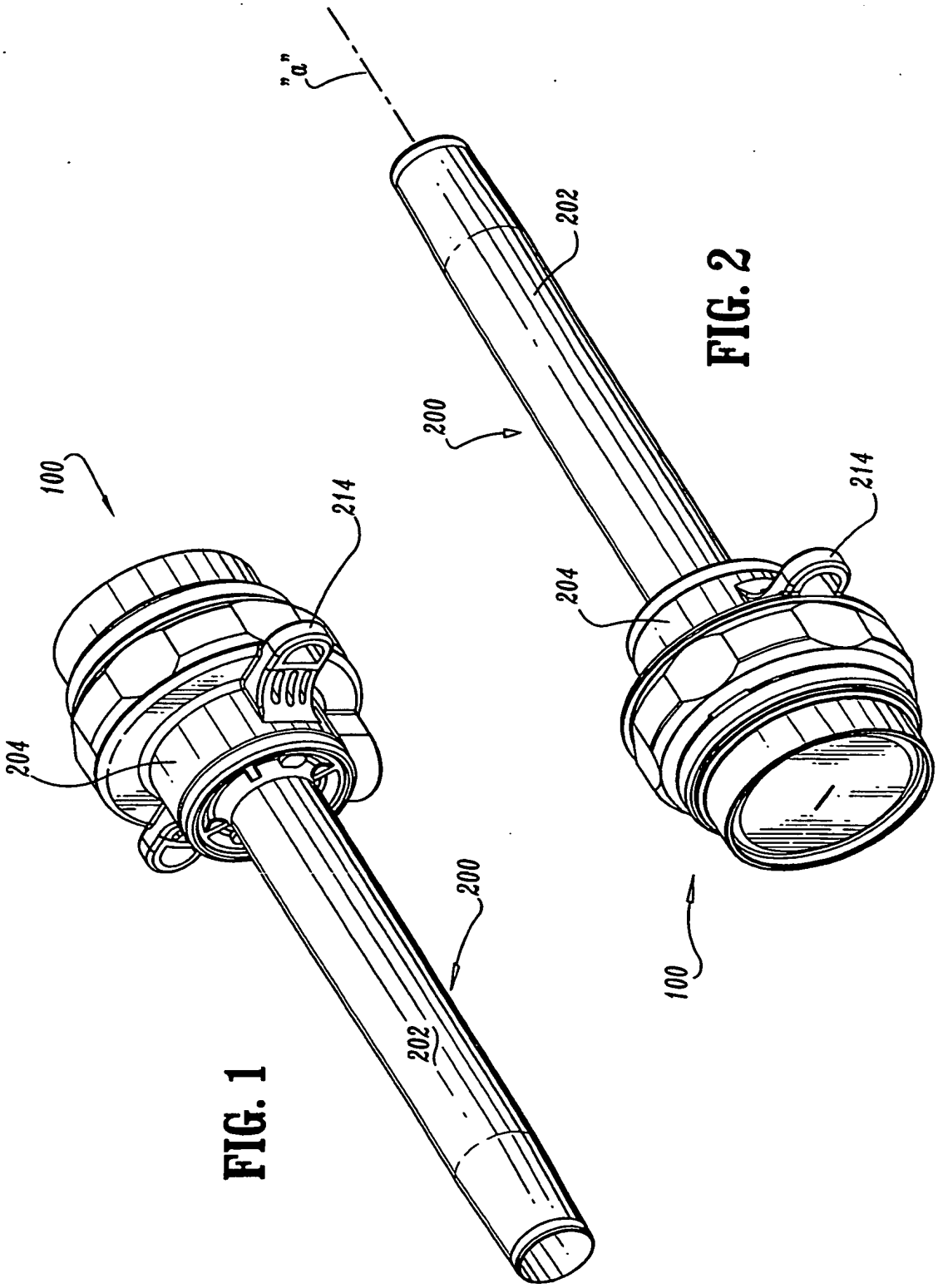

FIG. 1

FIG. 2

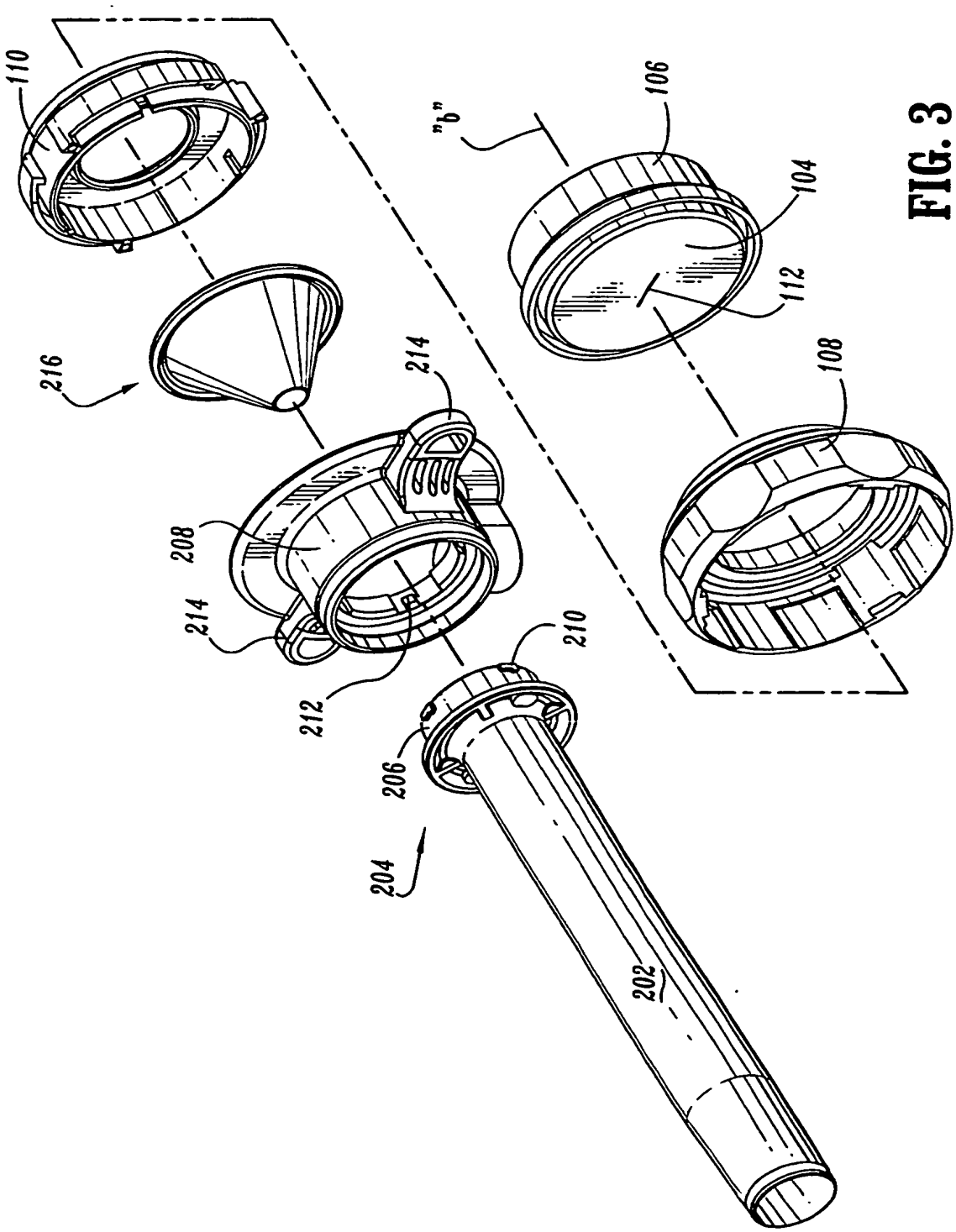

FIG. 3

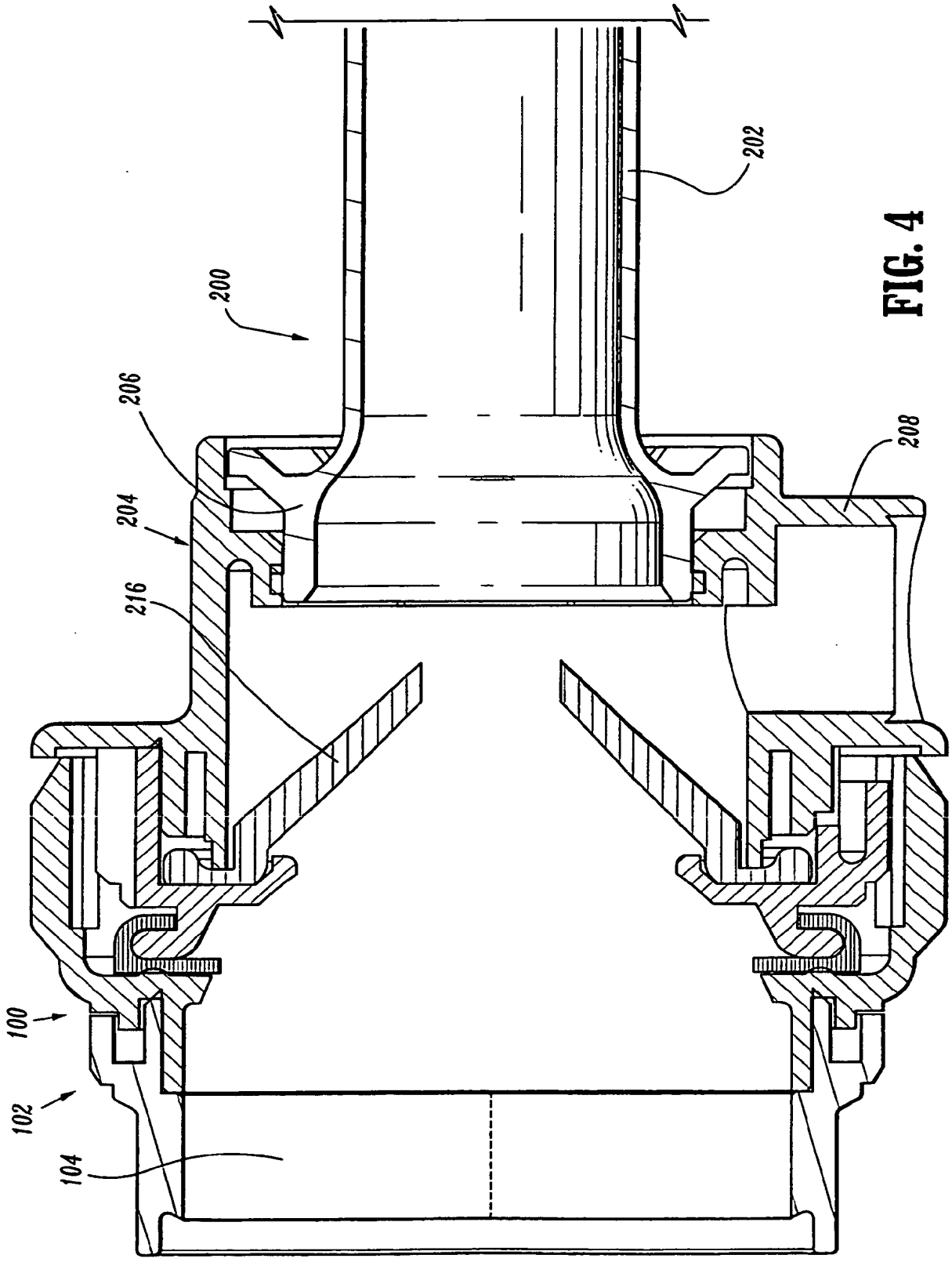

FIG. 4

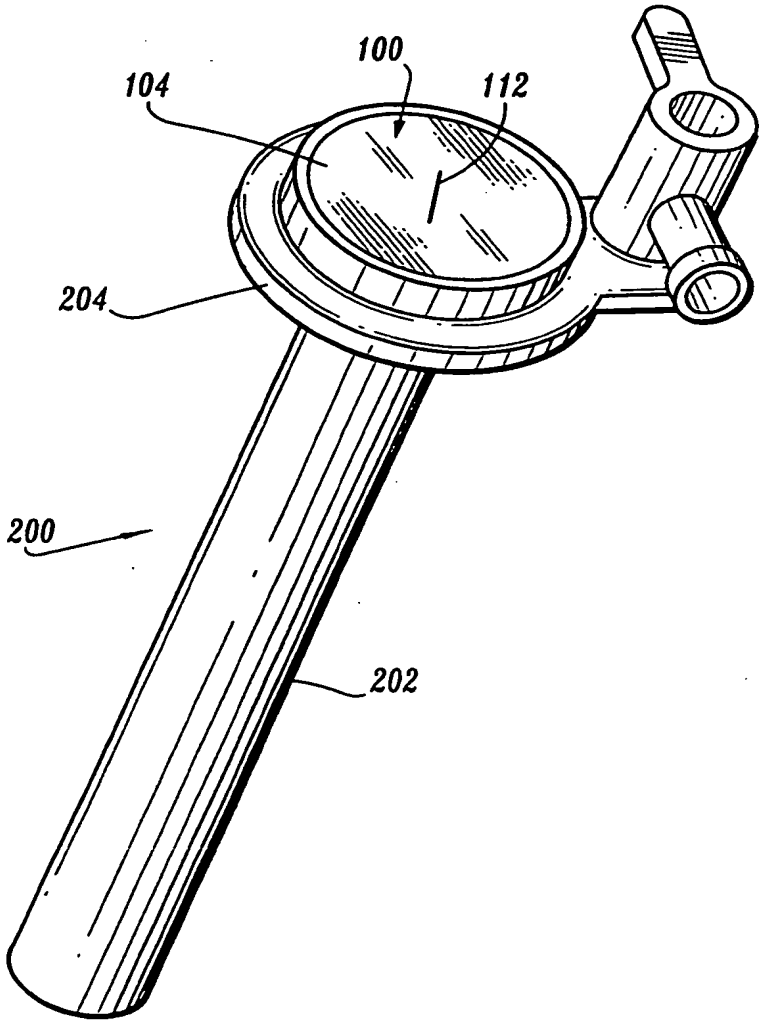

FIG. 5

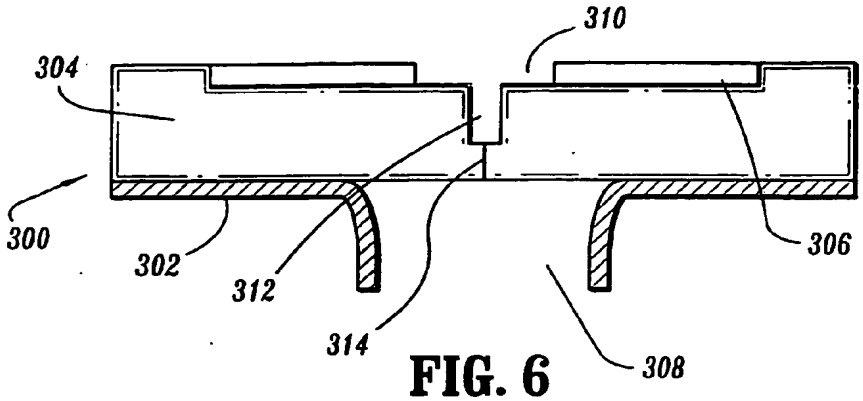

FIG. 6

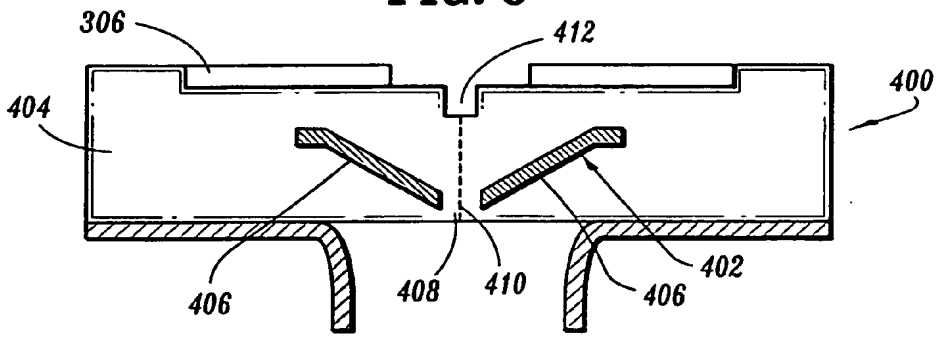

FIG. 7

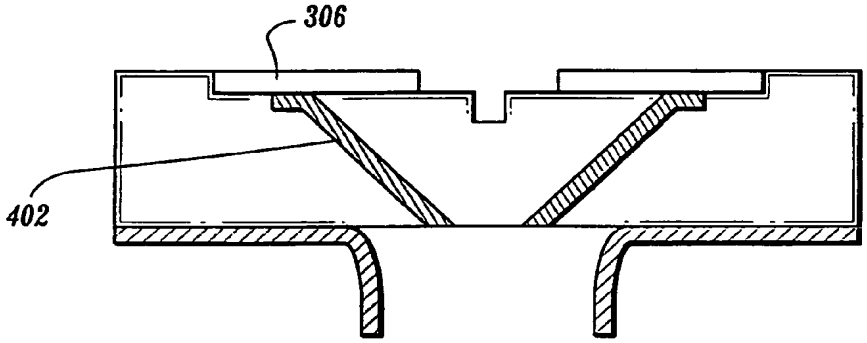

FIG. 8

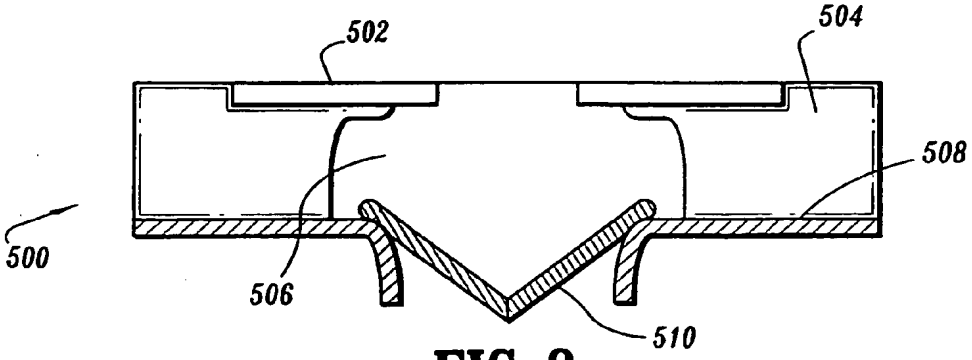

FIG. 9

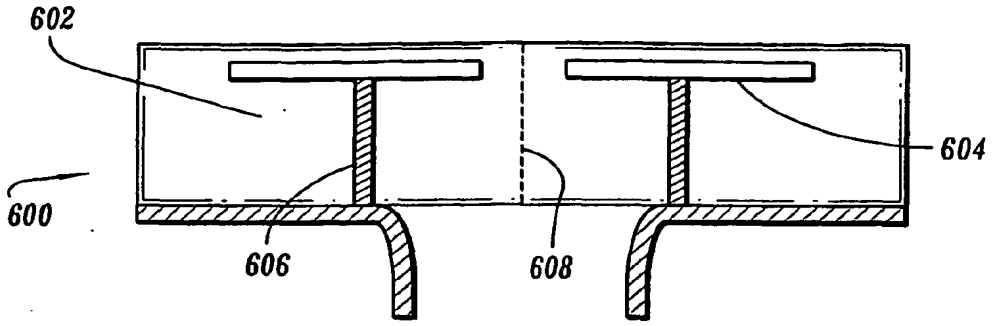

FIG. 10

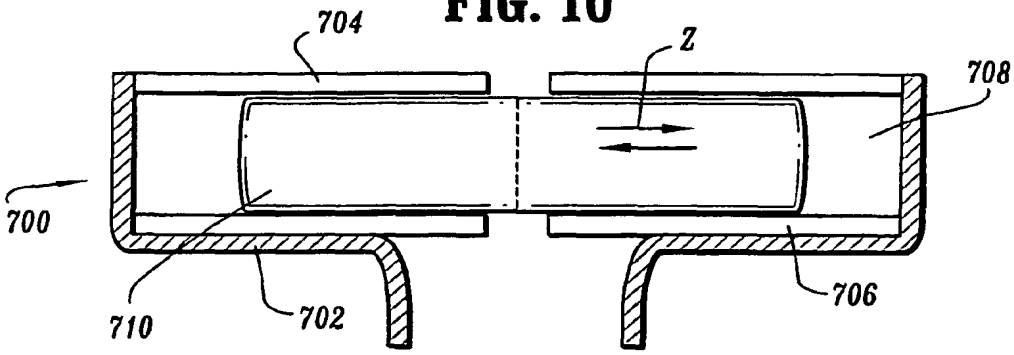

FIG. 11

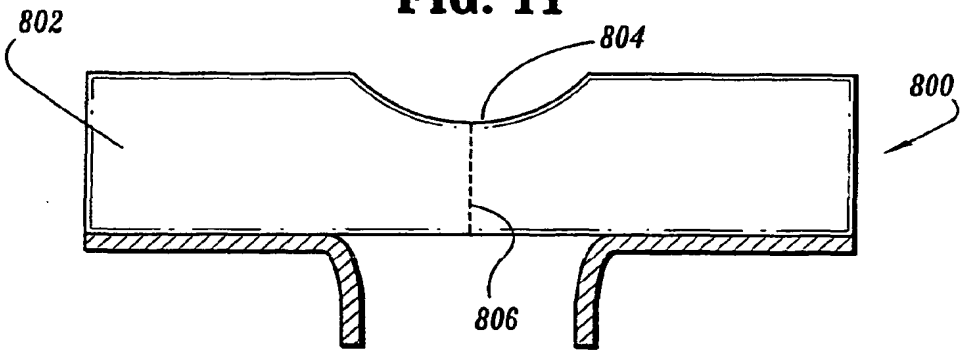

FIG. 12

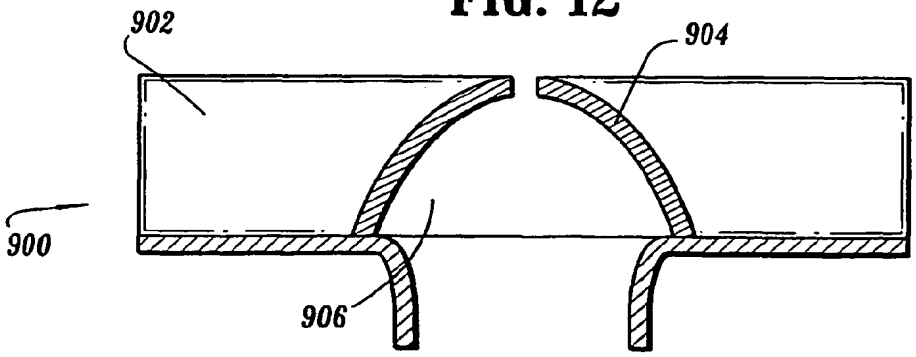

FIG. 13

REFERENCES CITED IN THE DESCRIPTION

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